

App. Docket No. PU35 Sw



23347

PATENT TRADEMARK OFFICE

TECH CENTER 1600/2900

MAR 24 2003

RECEIVED

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: Application of: Vincent C. KNICK et al.

Serial No.: 10/031,355

Art Unit: 1645

Filing Date: January 18, 2002

Examiner:

For: *Combination of an Anti-ep-cam Antibody  
With a Chemotherapeutic Agent*

P#8

BOX DD

Commissioner for Patents  
Washington, D.C. 20231

### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicants request that the references identified on Form PTO-1449 appended hereto be considered by the Examiner and officially made of record in accordance with the provisions of 37 CFR 1.97

- ☒ Copies of the references are enclosed  
☐ Copies of the references were submitted in parent application Serial No. \_\_\_\_\_. (37 CFR 1.98(d))  
☐ A copy of the International Search Report which issued on International Application No. \_\_\_\_\_ is submitted herewith. All of the publications cited in the International Search Report are listed on the attached form PTO-1449 and Applicants understand that copies have been supplied to the U.S. Patent Office by the International Bureau.

- A. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of the above application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 CFR 1.97(b).

OR

- ☐ The Information Disclosure Statement submitted herewith is being filed before the mailing of a first office action after the filing of a Request For Continued Examination under 37 C.F.R. 1.114 (37 C.F.R. 1.97(b)(4)).

- B. ☐ The Information Disclosure Statement transmitted herewith is being filed after three months of the filing date of the above application or the date of entry into the national stage as set forth in § 1.491 of an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last, but before the mailing date of either:
- (1) a final action under § 1.113 or
  - (2) a notice of allowance under § 1.311,
- whichever occurs first.

### CERTIFICATE OF MAILING (37 CFR 1.8)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: BOX DD, Commissioner for Patents, Washington, D.C. 20231.

Date; March 14, 2003

Marjorie J. Pfeiffer

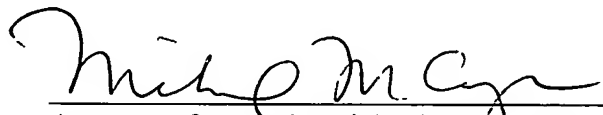
*Marjorie J. Pfeiffer*

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under § 1.97(c) (\$180.00).
- C. ☐ The Information Disclosure Statement transmitted herewith is being filed after a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before the payment of the issue fee. Also enclosed is a copy of the International Search Report which Issued on International Publication No.

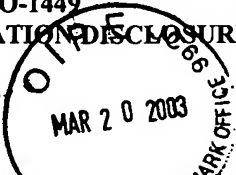
In accordance with the requirements of 37 CFR 1.97(d):

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ Applicant hereby petitions for the consideration of the accompanying Information Disclosure Statement. 37 CFR 1.97(d)(ii).
- ☐ The petition fee set forth in § 1.17(i)(1) (\$130.00) is submitted herewith.
- ☒ Please charge any required fees to Deposit Account No.07-1392.
- ☐ A duplicate copy of this paper is attached.

Respectfully Submitted,

  
Attorney of Record: Michael M. Conger  
Registration No. 43,562

Date: March 14, 2003  
GlaxoSmithKline  
Corporate Intellectual Property  
5 Moore Drive, P.O. Box 13398  
Research Triangle Park, NC 27709-3398  
Telephone: (919) 483-2474  
Facsimile: (919) 483-7988

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTORNEY DOCKET NO. PU3513USw	SERIAL NO. 10/031,355
		APPLICANT KNICK et al.	
		FILING DATE January 18, 2002	GROUP 1645

**U.S. PATENT DOCUMENTS**

Examiner Initials	Patent Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate

Continue on page \_\_\_\_\_

**FOREIGN PATENT DOCUMENTS**

	Document Number	Publication Date	Country	Class	Subclass	Translation Yes   No
1.	WO 87/00462		PCT			X (Abstract)
2.	WO 92/07075		PCT			

Continue on page \_\_\_\_\_

**OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)**

3.	Bebbington et al., "High-level expression of a recombinant antibody from myeloma cells using a glutamine synthetase gene as an amplifiable selectable marker," <i>Bio/Technology</i> 10:169-175 (Feb. 1992).
4.	Bhuyan et al., "Lethality, DNA alkylation, and cell cycle effects of adozelesin (U-73975) on rodent and human cells," <i>Cancer Research</i> 52(2):5687-5692 (Oct. 1992).
5.	Chen et al., "Differences in inhibition of chromosome separation and G <sub>2</sub> arrest by DNA topoisomerase II inhibitors merbarone and VM-26," <i>Cancer Research</i> 55(7):1509-1516 (Apr. 1995).
6.	Colcher et al., "A spectrum of monoclonal antibodies reactive human mammary tumor cells," <i>Proc. Natl. Acad. Sci. USA</i> 78(5):3199-3203 (May 1981).
7.	Czuczman et al., "IgM monoclonal antibody JD118 recognizes an inducible antigen target for human-complement-mediated cytotoxicity against neoplastic B cells," <i>Cancer Immunology, Immunotherapy</i> 36(6):387-396 (1993).
8.	Ellis et al., "Engineered anti-CD38 monoclonal antibodies for immunotherapy of multiple myeloma," <i>The Journal of Immunology</i> 155:925-937 (1995).
9.	Engelholm et al., "Effect of Melphalan on growth curves and cell cycle distribution of four human small cell carcinomas of the lung grown in nude mice," <i>Experimental Cell Biology</i> 54(3):138-148 (1986).
10.	Erba et al., "Comparison of cell-cycle phase perturbations induced by the DNA-minor-groove alkylator tallimustine and by melphalan in the SW626 cell line," <i>International Journal of Cancer</i> 62(2):170-175 (Jul. 1995).
11.	Fargion et al., "Heterogeneity of cell surface antigen expression of human small cell lung cancer detected by monoclonal antibodies," <i>Cancer Research</i> 46:2633-2638 (May 1986).
12.	Fogler et al., "Enhanced cytotoxicity against colon carcinoma by combinations of noncompeting monoclonal antibodies to the 17-1A antigen," <i>Cancer Research</i> 48:6303-6308 (1988).
13.	Greiner et al., "Enhanced expression of surface tumor-associated antigens on human breast and colon tumor cells after recombinant human leukocyte $\alpha$ -interferon treatment," <i>Cancer Research</i> 44:3208-3214 (Aug. 1984).
14.	Greiner et al., "Intraperitoneal administration of interferon-gamma to carcinoma patients enhances expression of tumor-associated glycoprotein-72 and carcinoembryonic antigen on malignant ascites cells," <i>J. Clin Oncol</i> 10(5):735-746 (May 1992).
15.	Herlyn et al., "CO 17-1A and related monoclonal antibodies: their production and characterization," <i>Hybridoma</i> 5(Suppl. 1):S3-S10 (1986).
16.	Herlyn et al., "Colorectal carcinoma-specific antigen: detection by means of monoclonal antibodies," <i>Proc. Natl. Acad. Sci. USA</i> 76(3):1438-1452 (Mar. 1979).
17.	Inaba et al., "Flow cytometric analysis of cell-killing actions of 5-fluorouracil in human colorectal cancer cells," <i>Oncology Research</i> 6(7):303-309 (1994).
18.	Jones et al., "Replacing the complementarity-determining regions in a human antibody with those from a mouse," <i>Nature</i> 321:522 (May 1986).

Continue on page 2

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

RECEIVED  
 MAR 24 2003  
 TECH CENTER 160125000  
 Page 1 of 1

**FORM PTO-1449**  
**INFORMATION DISCLOSURE STATEMENT**
**ATTORNEY CHECK NO.**  
 PU3513USw

**SERIAL NO.**  
 10/031,355

**APPLICANT**  
 KNICK et al.

**FILING DATE**  
 January 18, 2002

**GROUP**  
 1645

**U.S. PATENT DOCUMENTS**

Examiner Initials	Patent Number	Issue Date	Name	Class	Subclass	Filing Date Appr. Date

Continue on page \_\_\_\_

**FOREIGN PATENT DOCUMENTS**

Document Number	Publication Date	Country	Class	Subclass	Translation Yes   No

Continue on page \_\_\_\_

**OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)**

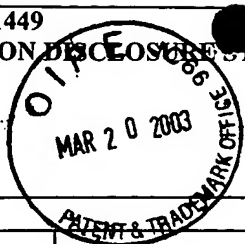
19.	Kallio et al., "Effects of the DNA topoisomerase II inhibitor merbarone in male mouse meiotic divisions in vivo: Cell cycle arrest and induction of aneuploidy," <i>Environmental &amp; Molecular Mutagenesis</i> <b>29</b> (1):16-27 (1997).
20.	Klucar et al., "G2 cell cycle arrest and apoptosis are induced in Burkitt's lymphoma cells by the anticancer agent oracin," <i>FEBS Letters</i> <b>400</b> (1):127-130 (Jan. 1997).
21.	Laio et al., "Binding and functional properties of a mouse-human chimeric monoclonal antibody of the human IgG1 subclass with specificity for human carcinomas," <i>Human Antibody Hybridomas</i> <b>1</b> (2):66-76 (1990).
22.	Litvinow et al., "Ep-CAM: a human epithelial antigen is a homophilic cell-cell adhesion molecule," <i>J. Cell Biology</i> <b>125</b> :437-446 (1994).
23.	Okabe et al., "Monoclonal antibodies to surface antigens of small cell carcinoma of the lung," <i>Cancer Research</i> <b>44</b> :5273-5278 (Nov. 1984).
24.	Reichmann et al., "Reshaping human antibodies for therapy," <i>Nature</i> <b>332</b> :323-327 (Mar. 1988).
25.	Riethmuller et al., "Monoclonal antibodies in the detection and therapy of micrometastatic epithelial cancers," <i>Curr. Opin. Immun.</i> <b>4</b> :647-655 (1992).
26.	Riethmuller et al., "Monoclonal antibodies in cancer therapy," <i>Curr. Opin. Immun.</i> <b>5</b> :732-739 (1993).
27.	Rojas et al., "Genotoxic effects of bistratene A on human lymphocytes," <i>Mutation Research</i> <b>367</b> (3):169-175 (Mar. 1996).
28.	Song, "Expression of sarcoma-associated antigens p102 and p200 in human sarcoma cell lines," <i>Anticancer Research</i> <b>16</b> (3A):1171-1175 (1996).
29.	Stephens et al., "The construction of a highly efficient and versatile set of mammalian expression vectors," <i>Nucleic Acid Res.</i> <b>17</b> (17):7110 (1989).
30.	Tyle, "Ionophoretic devices for drug delivery," <i>Pharmaceutical Research</i> <b>3</b> (6):318-326 (1986).
31.	Verhoeyen et al., "Reshaping human antibodies: grafting an antilysozyme activity," <i>Science</i> <b>239</b> :1534-1536 (Mar. 1988).
32.	Watters et al., "Accumulation of HL-60 leukemia cells in G2/M and inhibition of cytokinesis caused by two marine compounds, bistratene A and cyclozoline," <i>Cancer Chemotherapy &amp; Pharmacology</i> <b>33</b> (5):399-409 (1994).
33.	Wei et al., "Expression of the surface antigen in human gastric cancer cells and the relation to cell cycles," <i>J of Oncology</i> <b>9</b> (3):179-182 (1987) (Abstract).
34.	Wulf et al., "A cell-surface epitope associated with liver-preferential metastasis detected by the new monoclonal antibody 3H4 in the murine tumor model ER 15-P," <i>J Cancer Research and Clinical Oncology</i> <b>122</b> (8):476-482 (1996).

Continue on page \_\_\_\_

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.


 TECH CENTER 1  
 MAR 24 2003

RECEIVED